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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,079	08/06/2003	Janet K. Yamamoto	UF-152FWCD2	1433
23557	7590	03/22/2006	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			CHEN, STACY BROWN	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/636,079	<b>Applicant(s)</b> YAMAMOTO, JANET K.	
	<b>Examiner</b> Stacy B. Chen	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 31-43 and 50-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-36, 38-43 and 50-63 is/are ~~allowed~~ allowable. *SBC 3/13/06*
- 6) ☒ Claim(s) 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's amendment filed December 27, 2005 is acknowledged and entered. Claims 31-43 and 50-63 are pending and under examination.
2. The rejection of claims 31-35, 50, 51, 53-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto *et al.* (US 5,275,813, " '813 Patent ") in view of Sodora *et al.* (*Journal of Virology*, 1994, 68(4):2230-2238, " Sodora ") and Zagury *et al.* (WO 92/00098, " Zagury ") is withdrawn in view of Applicant's persuasive arguments. Applicant argues that even if it were obvious to combine the teachings of the '813 Patent, Sodora and Zagury, Applicant surprisingly discovered that the combination of various FIV subtypes results in a protective immune response against FIV infection by less closely related heterologous strains, including strains that are of a subtype not present in the vaccine composition. (For example, a combination of subtypes A and D induces a protective immune response against subtype B). This result is surprising because one would expect a combination of A and D to induce an immune response against A and D, not B, and certainly not a protective immune response. Likewise, the rejection of claim 52 under 35 U.S.C. 103(a) as being unpatentable over the '813 Patent in view of Sodoro and Zagary as applied to claims 31-35, 50 and 51 above, and further in view of Yamamoto *et al.* (*Journal of Virology*, 1993, 67(1):601-605, " Yamamoto ") is withdrawn in view of Applicant's persuasive arguments.

***Claim Rejections - 35 USC § 112***

3. Claim 37 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is apparent that the FIV strains *Dix*, *UK8*, *Aom1* and *Aom2* are required to practice the claimed invention because they are a necessary limitation for the success of the invention as stated in claim 37. (Previously, the Office asserted that the *Pet* strain was unavailable, however, Applicant notes that the *Petulama* strain was deposited with the ATCC under accession number VR-1312. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of *Dix*, *UK8*, *Aom1* and *Aom2*. See 37 CFR 1.802. One cannot practice the claimed invention without these strains. Therefore, access to *Dix*, *UK8*, *Aom1* and *Aom2* is required to practice the invention. The specification does not provide a repeatable method for obtaining *Dix*, *UK8*, *Aom1* and *Aom2* without access to the *Dix*, *UK8*, *Aom1* and *Aom2* and they do not appear to be readily available material.

Deposit of *Dix*, *UK8*, *Aom1* and *Aom2* in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112, because the strains would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809.

Applicant's arguments have been carefully considered but fail to persuade. Applicant indicates the FIV strain Dixon is available at Genbank under accession number L00608. Also,

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sequence information for the UK8 and Aomori strains of FIV is also available at Genbank.

Applicant argues that a person of ordinary skill in the art can readily make and use the FIV strains recited in the claim.

In response to this argument, Genbank sequences are not irrevocably fixed but are corrected and updated as additional sequence information becomes available, the Genbank accession number may refer to sequences which change after the application filing date. Lacking a full-length sequence of the virus (a definite sequence), or a deposit, the claim remains rejected for lacking adequate written description.

#### ***Double Patenting***

4. Claims 37, 42 and 43 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 4 of U.S. Patent No. 5,846,825. Although the conflicting claims are not identical, they are not patentably distinct from each other because the active ingredients of the instant claims and the patented claims are drawn to deposited FIV-infected cell lines of at least FIV strains *Dix*, *UK8*, *Bang*, *Aom1*, *Aom2*, *Shi*, and *Pet*. Because claims 2 and 4 include at least one of these strains (thus encompassing more than one strain) the patented claims are encompassed by instant claims 37, 42 and 43.

Applicant has indicated that the filing of a terminal disclaimer will be considered once allowable material is indicated.

***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

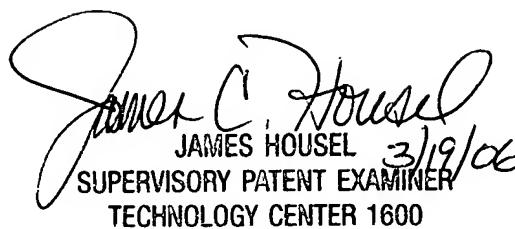
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-

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272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen  
March 13, 2006



JAMES HOUSEL 3/19/06  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600